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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/579,168 | 08/18/2006 | Karl Mulligan | 36290-0409-00-US | 8905 |

23973 7590 05/01/2007

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

| EXAMINER | |
|---|---|
| SHEN, WU CHENG WINSTON | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |
| **MAIL DATE** | **DELIVERY MODE** |
| 05/01/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/579,168 | MULLIGAN ET AL. | |
| | Examiner | Art Unit | |
| | Wu-Cheng Winston Shen | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-38 are pending in the instant application.

### *Election/Restrictions*

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-3, drawn to an isolated nucleic acid sequence which comprises a sequence selected from the group consisting of: Sequence ID No. 1, Sequence ID No. 2, and sequence ID No 3.

II Claims 32-36, drawn to a polynucleotide that is *anti-sense* to an isolated nucleic acid sequence of any claim 1; a method of treating cancer in an individual by inducing apoptosis in cells in the individual which express an MQ 1 protein, which method comprises a step of treating an individual with an anti-sense polynucleotide of any of claims 32 to 34.

III. Claims 4-7, 37, and 38, drawn to an isolated protein encoded by a nucleic acid sequence according to claim 1; an isolated protein encoded by a nucleic acid sequence

according to claim 2; an isolated protein encoded by a nucleic acid sequence according to claim 3.

IV. Claims 8-11, and 19-31 (in part), drawn to an antibody which binds specifically to the protein of claim 4, and any other antibody that competes directly or by steric hindrance therewith for said protein; and a method of detecting an astrocytoma cell in a sample of human cells, which method comprises the step of contacting the cell sample with an antibody according to claim 8, or a fragment thereof, and detecting those cells which have bound the antibody or fragment, wherein binding of the antibody or the fragment to a cell is indicative of an astrocytoma cell; a method of detecting a primary breast carcinoma cell in a sample of human cells, which method comprises the step of contacting the cell sample with an antibody according to claim 8, or a fragment thereof, and detecting those cells which have bound the antibody or fragment, wherein binding of the antibody or the fragment to a cell is indicative of a primary breast carcinoma cell; a diagnostic kit for diagnosing the presence of a cell selected from the group consisting of: astrocytoma cells; malignant melanoma secondary tumor cells; and primary breast carcinoma cells, the kit comprising a (primary) antibody according to claim 18, or a fragment thereof; a biological targeting device comprising an antibody according to claim 18, or a fragment thereof, and a therapeutic ligand; a therapeutic antibody comprising an antibody according to claim 18, or a fragment thereof; a method of treating cancer in an individual by inducing apoptosis in cells

in the individual which express an MQ1 protein, which method comprises a step of treating an individual with an antibody of any claim18, or a fragment thereof.

V. Claim 12, drawn to a method of producing a polyclonal antibody to a protein comprising: inoculating an animal with a protein according to claim 4, wherein the protein elicits an immune response in the animal to produce the antibody; and isolating the antibody from the animal.

VI. Claim 13, drawn to a method of producing a polyclonal antibody as claimed in Claim 12 in which the animal is inoculated with G-CCM cells of ECACC deposit No. 86022702.

VII. Claims 14 and 16 (in part), drawn to a method for producing a hybridoma, comprising the step of inoculating a suitable subject with a protein according to claim 4, or an antigenic fragment thereof, and fusing cells from the subject with a myeloma cell to produce the hybridoma; and a hybridoma cell obtainable according to the method of claim 14.

VIII. Claims 15 and 16 (in part), drawn to a method according to claim 14 in which the subject is inoculated with G-CCM cells of ECACC deposit No. 86022702; and a hybridoma cell obtainable according to the method of claim 15.

IX. Claim 17, drawn to a hybridoma cell of, or derived from, ECACC Deposit No. 03073001.

X. Claims 18, and 19-31 (in part), drawn to a monoclonal antibody obtainable from a hybridoma cell of, or derived from, ECACC Deposit No. 03073001; a method of detecting an astrocytoma cell in a sample of human cells, which method

comprises the step of contacting the cell sample with an antibody according to claim 18, or a fragment thereof, and detecting those cells which have bound the antibody or fragment, wherein binding of the antibody or the fragment to a cell is indicative of an astrocytoma cell; a method of detecting a primary breast carcinoma cell in a sample of human cells, which method comprises the step of contacting the cell sample with an antibody according to claim 18, or a fragment thereof, and detecting those cells which have bound the antibody or fragment, wherein binding of the antibody or the fragment to a cell is indicative of a primary breast carcinoma cell; a diagnostic kit for diagnosing the presence of a cell selected from the group consisting of: astrocytoma cells; malignant melanoma secondary tumor cells; and primary breast carcinoma cells, the kit comprising a (primary) antibody according to claim 18, or a fragment thereof; a biological targeting device comprising an antibody according to claim 18, or a fragment thereof, and a therapeutic ligand; a therapeutic antibody comprising an antibody according to claim 18, or a fragment thereof; a method of treating cancer in an individual by inducing apoptosis in cells in the individual which express an MQ1 protein, which method comprises a step of treating an individual with an antibody of any claim18, or a fragment thereof.

3. Additionally, each group named above is subject to further restriction. Applicant is required to further elect a specific SEQ ID NO from (the claim, table, etc), [or a specific combination of... to which the claims will be limited]. This is **NOT** an election of species.

Structurally distinct nucleotide sequences are distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

4. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The common technical feature in all groups, as stated in claim 1, is an isolated nucleic acid sequence which comprises a sequence selected from the group consisting of: Sequence ID No. 1, Sequence ID No. 2, and sequence ID No 3. SEQ ID No. 1, 2, and 3 are splice variants of cDNA clones encoding MQ1 cell surface glycoprotein of Astrocytoma cell. However, this common technical

feature of a cDNA encoding an MQ1 cell surface glycoprotein of an astrocytoma cell cannot be a special technical feature under PCT Rule 13.2 because the feature is shown in the prior art.

As listed in the following pages 7-9, Genebank database locus AF028593 reads on the recited SEQ ID No: 1 of instant application.

gb|AF028593.1|AF028593 Homo sapiens transmembrane protein Jagged 1 (HJ1) mRNA, complete cds
Length=5457

Score = 4327 bits (2183), Expect = 0.0
Identities = 2270/2270 (100%), Gaps = 0/2270 (0%)
Strand=Plus/Plus

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Query  1     GCTCAGAATACCAATGACTGCAGCCCTCATCCCTGTTACAACAGCGGCACCTGTGTGGAT  60
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  2601  GCTCAGAATACCAATGACTGCAGCCCTCATCCCTGTTACAACAGCGGCACCTGTGTGGAT  2660

Query  61    GGAGACAACTGGTACCGGTGCGAATGTGCCCCGGGTTTTGCTGGGCCCGACTGCAGAATA  120
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  2661  GGAGACAACTGGTACCGGTGCGAATGTGCCCCGGGTTTTGCTGGGCCCGACTGCAGAATA  2720

Query  121   AACATCAATGAATGCCAGTCTTCACCTTGTGCCTTTGGAGCGACCTGTGTGGATGAGATC  180
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  2721  AACATCAATGAATGCCAGTCTTCACCTTGTGCCTTTGGAGCGACCTGTGTGGATGAGATC  2780

Query  181   AATGGCTACCGGTGTGTCTGCCCTCCAGGGCACAGTGGTGCCAAGTGCCAGGAAGTTTCA  240
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Sbjct  2781  AATGGCTACCGGTGTGTCTGCCCTCCAGGGCACAGTGGTGCCAAGTGCCAGGAAGTTTCA  2840

Query  241   GGGAGACCTTGCATCACCATGGGGAGTGTGATACCAGATGGGGCCAAATGGGATGATGAC  300
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Sbjct  2841  GGGAGACCTTGCATCACCATGGGGAGTGTGATACCAGATGGGGCCAAATGGGATGATGAC  2900

Query  301   TGTAATACCTGCCAGTGCCTGAATGGACGGATCGCCTGCTCAAAGGTCTGGTGTGGCCCT  360
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Sbjct  2901  TGTAATACCTGCCAGTGCCTGAATGGACGGATCGCCTGCTCAAAGGTCTGGTGTGGCCCT  2960

Query  361   CGACCTTGCCTGCTCCACAAAGGGCACAGCGAGTGCCCCAGCGGGCAGAGCTGCATCCCC  420
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Sbjct  2961  CGACCTTGCCTGCTCCACAAAGGGCACAGCGAGTGCCCCAGCGGGCAGAGCTGCATCCCC  3020

Query  421   ATCCTGGACGACCAGTGCTTCGTCCACCCCTGCACTGGTGTGGGCGAGTGTCGGTCTTCC  480
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Sbjct  3021  ATCCTGGACGACCAGTGCTTCGTCCACCCCTGCACTGGTGTGGGCGAGTGTCGGTCTTCC  3080

Query  481   AGTCTCCAGCCGGTGAAGACAAAGTGCACCTCTGACTCCTATTACCAGGATAACTGTGCG  540
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Sbjct  3081  AGTCTCCAGCCGGTGAAGACAAAGTGCACCTCTGACTCCTATTACCAGGATAACTGTGCG  3140

Query  541   AACATCACATTTACCTTTAACAAGGAGATGATGTCACCAGGTCTTACTACGGAGCACATT  600
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Sbjct  3141  AACATCACATTTACCTTTAACAAGGAGATGATGTCACCAGGTCTTACTACGGAGCACATT  3200

Query  601   TGCAGTGAATTGAGGAATTTGAATATTTTGAAGAATGTTTCCGCTGAATATTCAATCTAC  660
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Sbjct  3261  ATCGCTTGCGAGCCTTCCCCTTCAGCGAACAATGAAATACATGTGGCCATTTCTGCTGAA  3320

Query  721   GATATACGGGATGATGGGAACCCGATCAAGGAAATCACTGACAAAATAATCGATCTTGTT  780
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Sbjct  3321  GATATACGGGATGATGGGAACCCGATCAAGGAAATCACTGACAAAATAATCGATCTTGTT  3380

Query  781   AGTAAACGTGATGGAAACAGCTCGCTGATTGCTGCCGTTGCAGAAGTAAGAGTTCAGAGG  840
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Sbjct  3381  AGTAAACGTGATGGAAACAGCTCGCTGATTGCTGCCGTTGCAGAAGTAAGAGTTCAGAGG  3440

Query  841   CGGCCTCTGAAGAACAGAACAGATTTCCTTGTTCCCTTGCTGAGCTCTGTCTTAACTGTG  900
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Sbjct  3441  CGGCCTCTGAAGAACAGAACAGATTTCCTTGTTCCCTTGCTGAGCTCTGTCTTAACTGTG  3500

Query  901   GCTTGGATCTGTTGCTTGGTGACGGCCTTCTACTGGTGCCTGCGGAAGCGGCGGAAGCCG  960
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Sbjct  3501  GCTTGGATCTGTTGCTTGGTGACGGCCTTCTACTGGTGCCTGCGGAAGCGGCGGAAGCCG  3560

Query  961   GGCAGCCACACACACTCAGCCTCTGAGGACAACACCACCAACAACGTGCGGGAGCAGCTG  1020
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Sbjct  3561  GGCAGCCACACACACTCAGCCTCTGAGGACAACACCACCAACAACGTGCGGGAGCAGCTG  3620

Query  1021  AACCAGATCAAAAACCCCATTGAGAAACATGGGGCCAACACGGTCCCCATCAAGGATTAT  1080
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  3621  AACCAGATCAAAAACCCCATTGAGAAACATGGGGCCAACACGGTCCCCATCAAGGATTAT  3680

Query  1081  GAGAACAAGAACTCCAAAATGTCTAAAATAAGGACACACAATTCTGAAGTAGAAGAGGAC  1140
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Sbjct  3681  GAGAACAAGAACTCCAAAATGTCTAAAATAAGGACACACAATTCTGAAGTAGAAGAGGAC  3740

Query  1141  GACATGGACAAACACCAGCAGAAAGCCCGGTTTGCCAAGCAGCCGGCGTACACGCTGGTA  1200
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Sbjct  3741  GACATGGACAAACACCAGCAGAAAGCCCGGTTTGCCAAGCAGCCGGCGTACACGCTGGTA  3800

Query  1201  GACAGAGAAGAGAAGCCCCCCAACGGCACGCCGACAAAACACCCAAACTGGACAAACAAA  1260
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Sbjct  3801  GACAGAGAAGAGAAGCCCCCCAACGGCACGCCGACAAAACACCCAAACTGGACAAACAAA  3860

Query  1261  CAGGACAACAGAGACTTGGAAAGTGCCCAGAGCTTAAACCGAATGGAGTACATCGTATAG  1320
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Sbjct  3861  CAGGACAACAGAGACTTGGAAAGTGCCCAGAGCTTAAACCGAATGGAGTACATCGTATAG  3920

Query  1321  CAGACCGCGGGCACTGCCGCCGCTAGGTAGAGTCTGAGGGCTTGTAGTTCTTTAAACTGT  1380
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Sbjct  4041  TGACAAGCTGGCTTACACTGGCAATGGTAGTTTCTGTGGTTGGCTGGGAAATCGAGTGCC  4100

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Sbjct  4161  CCGACACGGTCTCGGATCAGGCTCCCAGGAGCCTGCCCAGCCCCCTGGTCTTTGAGCTCC  4220

Query  1621  CACTTCTGCCAGATGTCCTAATGGTGATGCAGTCTTAGATCATAGTTTTATTTATATTTA  1680
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Sbjct  4221  CACTTCTGCCAGATGTCCTAATGGTGATGCAGTCTTAGATCATAGTTTTATTTATATTTA  4280

Query  1681  TTGACTCTTGAGTTGTTTTTGTATATTGGTTTTATGATGACGTACAAGTAGTTCTGTATT  1740
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Sbjct  4281  TTGACTCTTGAGTTGTTTTTGTATATTGGTTTTATGATGACGTACAAGTAGTTCTGTATT  4340

Query  1741  TGAAAGTGCCTTTGCAGCTCAGAACCACAGCAACGATCACAAATGACTTTATTATTTAtt  1800
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Sbjct  4341  TGAAAGTGCCTTTGCAGCTCAGAACCACAGCAACGATCACAAATGACTTTATTATTTATT  4400

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Sbjct  4401  TTTTTTAATTGTATTTTTGTTGTTGGGGGAGGGGAGACTTTGATGTCAGCAGTTGCTGGT  4460

Query  1861  AAAATGAAGAATTTAAAGaaaaaaaTGTCAAAAGTAGAACTTTGTATAGTTATGTAAATA  1920
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Sbjct  4461  AAAATGAAGAATTTAAAGAAAAAAATGTCAAAAGTAGAACTTTGTATAGTTATGTAAATA  4520

Query  1921  ATTCTTTTTTATTAATCACTGTGTATATTTGATTTATTAACTTAATAATCAAGAGCCTTA  1980
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Query  2041  GTAAGCGTATGGCTTTAttttttttGAACTCTTCTCATTACTTGTTGCCTATAAGCCAAAA  2100
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Sbjct  4641  GTAAGCGTATGGCTTTATTTTTTTGAACTCTTCTCATTACTTGTTGCCTATAAGCCAAAA  4700

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Sbjct  4761  CTGATGGAATTTTTTTGTACGACGTCAGATGTTTAAAACACCTTCTATAGCATCACTTAA  4820

Query  2221  AACACGTTTTAAGGACTGACTGAGGCAGTTTGAGGATTAGTTTAGAACAG  2270
              ||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct  4821  AACACGTTTTAAGGACTGACTGAGGCAGTTTGAGGATTAGTTTAGAACAG  4870
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5. This application contains claims directed to the following patentably distinct species: malignant astrocytomas; malignant melanoma secondary tumors; and primary breast carcinomas

(claim 36). The species are independent or distinct because they are distinct cancer cells at different stages of tumor development that requires different steps and technical considerations for a method of treatment.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim **36** is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

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Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632